

Reshma KOTIAN *et al.*
Serial No. 10/768,348
"Stabilized Paroxetine Formulation"

IN THE CLAIMS

26. (Amended) A moisture barrier, non-controlled release pharmaceutical excipient solution comprising:

- 5 A) ethylcellulose;
 B) polar solvent;
 C) alcohol; and
 D) a surfactant.

10 27. (Original) The moisture barrier pharmaceutical excipient of claim 26, wherein said surfactant comprises polysorbate 80, and wherein said polysorbate 80 and said ethylcellulose are present in a ratio of approximately 1.00 : 0.165.

28. (Amended) A process for manufacturing a substantially moisture stable, non-controlled release pharmaceutical product, comprising:

- 15 A) mixing ethylcellulose, polar solvent, alcohol and a surfactant to make a moisture barrier, non-controlled release pharmaceutical excipient solution;
 B) mixing a drug substance with said moisture barrier pharmaceutical excipient solution to form substantially moisture stable drug substance;
 C) coating the substantially moisture-resistant drug substance of step B in a pharmaceutically-acceptable coating.

20 29. (Original) The process of claim 28, wherein said pharmaceutically-acceptable coating comprises a gelatin capsule.

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30. (Original) The process of claim 28, wherein said surfactant comprises polysorbate 80, and wherein said polysorbate 80 and said ethylcellulose are present in a ratio of approximately 1.00 : 0.165.

31. (Original) The process of claim 28, wherein said drug substance comprises paroxetine.

32. (Original) The process of claim 3, wherein said surfactant comprises polysorbate 80, and wherein said polysorbate 80 and said ethylcellulose are present in a ratio of approximately 1.00 : 0.165, and wherein said drug substance comprises paroxetine.

33. (Amended) A substantially moisture stable, non-controlled release drug product comprising:

A) A substantially moisture stable, non-controlled release core comprising a drug substance, ethylcellulose and a surfactant; and

B) An outer layer surrounding said core, said outer layer comprising a pharmaceutically acceptable material, said outer layer substantially free of said drug substance.

34. (Original) The drug product of claim 33, wherein:

A) said surfactant comprises polysorbate 80, and wherein said polysorbate 80 and said ethylcellulose are present in a ratio of approximately 1.00 : 0.165.

35. (Original) The drug product of claim 33, wherein:

A) said drug substance comprises paroxetine.

36. (Original) The drug product of claim 33, wherein:

A) said drug substance comprises paroxetine, said surfactant comprises polysorbate 80, and wherein said polysorbate 80 and said ethylcellulose are present in a ratio of approximately 1.00 : 0.165.

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